(3) Nonconfidential data or other information submitted by interested persons pertaining to the health assessment or health effects study;

(4) The protocol for the health effects study;

(5) A list of the individuals responsible for external peer review of the report of a health effects study, their comments, and ATSDR's response to the comments; and

(6) For health effects study, the notice announcing the availability of a draft final report for public review and comment, all comments received in response to the notice, and any responses to the comments by ATSDR.

(b) The record may contain a confidential portion which shall include all information determined to be confidential by the Administrator under this part.

(c) The Administrator may determine other documents are appropriate for inclusion in the record for health assessments or health effects studies.

(d) Predecisional documents, including draft documents, are not documents upon which ATSDR bases its conclusions in health assessments or health effects studies, and are not usually included in the record for health assessments or health effects studies.

(e) The record for ATSDR health assessments and health effects studies will be available for review, upon prior request, at ATSDR headquarters in Atlanta, Georgia.

(f) Nothing in this section is intended to imply that ATSDR's decisions to conduct health assessments or health effects studies, or the reports of health assessments or health effects studies, are subject to judicial review.

§ 90.14 Documentation and cost recovery.

(a) During all phases of ATSDR health assessments and health effects studies, documentation shall be completed and maintained to form the basis for cost recovery, as specified in section 107 of CERCLA.

(b) Where appropriate, the information and reports compiled by ATSDR pertaining to costs shall be forwarded to the appropriate EPA regional office for cost recovery purposes.

PART 93—PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT

Sec.

Subpart A—General

Subpart B—Definitions

Subpart C—Responsibilities of Institutions

COMPLIANCE AND ASSURANCES

AUTHORITY: 42 U.S.C. 216, 241, and 289b.

SOURCE: 70 FR 28384, May 17, 2005, unless otherwise noted.

§ 93.25 Organization of this part.

This part is subdivided into five subparts. Each subpart contains information related to a broad topic or specific audience with special responsibilities as shown in the following table.

In subpart . . .	You will find provisions related to . . .
A	General information about this rule.
B	Definitions of terms used in this part.
C	Responsibilities of institutions with PHS support.
D	Responsibilities of the U.S. Department of Health and Human Services and the Office of Research Integrity.

In subpart . . .	You will find provisions related to . . .
E	Information on how to contest ORI research misconduct findings and HHS administrative actions.

§ 93.50 Special terms.

This part uses terms throughout the text that have special meaning. Those terms are defined in Subpart B of this part.

Subpart A—General

§ 93.100 General policy.

(a) Research misconduct involving PHS support is contrary to the interests of the PHS and the Federal government and to the health and safety of the public, to the integrity of research, and to the conservation of public funds.

(b) The U.S. Department of Health and Human Services (HHS) and institutions that apply for or receive Public Health Service (PHS) support for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training share responsibility for the integrity of the research process. HHS has ultimate oversight authority for PHS supported research, and for taking other actions as appropriate or necessary, including the right to assess allegations and perform inquiries or investigations at any time. Institutions and institutional members have an affirmative duty to protect PHS funds from misuse by ensuring the integrity of all PHS supported work, and primary responsibility for responding to and reporting allegations of research misconduct, as provided in this part.

§ 93.101 Purpose.

The purpose of this part is to—

(a) Establish the responsibilities of HHS, PHS, the Office of Research Integrity (ORI), and institutions in responding to research misconduct issues;

(b) Define what constitutes misconduct in PHS supported research;

(c) Define the general types of administrative actions HHS and the PHS may take in response to research misconduct; and

(d) Require institutions to develop and implement policies and procedures for—

(1) Reporting and responding to allegations of research misconduct covered by this part;

(2) Providing HHS with the assurances necessary to permit the institutions to participate in PHS supported research.

(e) Protect the health and safety of the public, promote the integrity of PHS supported research and the research process, and conserve public funds.

§ 93.102 Applicability.

(a) Each institution that applies for or receives PHS support for biomedical or behavioral research, research training or activities related to that research or research training must comply with this part.

(b)(1) This part applies to allegations of research misconduct and research misconduct involving:

(i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;

(ii) PHS supported biomedical or behavioral extramural or intramural research;

(iii) PHS supported biomedical or behavioral extramural or intramural research training programs;

(iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and

(v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.

(2) This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for